4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-1994-P-0314 (formerly Docket No. 94P-0168)]

Food Labeling: Serving Sizes; Reference Amount and Serving Size Declaration for Hard

Candies, Breath Mints

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is withdrawing a proposed rule entitled "Food Labeling; Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies, Breath Mints" that published in the <u>Federal Register</u> of December 30, 1997 (62 FR 67775). We are taking this action because we are issuing a proposed rule on the serving sizes of foods in general that is published elsewhere in this issue of the <u>Federal Register</u>.

DATES: The proposed rule that published on December 30, 1997 (62 FR 67775), is withdrawn as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Mark Kantor, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1450.

SUPPLEMENTARY INFORMATION:

I. Background

In the <u>Federal Register</u> of December 30, 1997, FDA published a proposed rule entitled "Food Labeling; Serving Sizes; Reference Amount and Serving Size Declaration for Hard

Candies, Breath Mints" (the 1997 breath mints proposed rule). The 1997 breath mints proposed rule would change the label serving size for the product category "Hard candies, breath mints" so that the serving size for all breath mint products would be one unit. The 1997 breath mints proposed rule was published, in part, in response to a citizen petition (Docket No. FDA-1994-P-0314 (formerly Docket No. 94P-0168)) that requested a serving size for breath mints that more accurately reflected the amount customarily consumed per eating occasion. Specifically, the petition requested that FDA create a separate product category with a 0.5-gram (g) reference amount for small breath mints (weighing 0.5 g or less). The petition concluded that the serving size for small breath mints should be "1 mint." The 1997 breath mints proposed rule also would amend the current rounding requirements for calories as described in 21 CFR 101.9(c)(1), which states that the caloric content per serving must be expressed to the nearest 5calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. The 1997 breath mints proposed rule would allow the declaration of calorie amounts of less than 5 calories on the Nutrition Facts label, provided that the number of calories declared on the Nutrition Facts label is consistent with the number of calories declared in any claim about the amount of calories made under 21 CFR 101.13(i).

In the <u>Federal Register</u> of April 4, 2005 (70 FR 17010), we issued an advance notice of proposed rulemaking (ANPRM) entitled "Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes." The ANPRM requested comment on whether we should amend certain nutrition labeling regulations concerning serving size.

In response to the ANPRM, elsewhere in this issue of the <u>Federal Register</u>, we are publishing a proposed rule that would, in part, amend the serving size for breath mints.

II. Withdrawal of the 1997 Proposed Rule

Because we are addressing issues related to the label serving size for breath mints, in conjunction with other serving size issues, in a proposed rule entitled, "Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments," published elsewhere in this issue of the Federal Register, we are withdrawing the 1997 breath mints proposed rule.

Dated: February 2	24,	2014.
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Leslie Kux,

Assistant Commissioner for Policy.

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